ONCOMED PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 17, 2017

ONCOMED PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-35993**	**38-3572512**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

800 Chesapeake Drive
Redwood City, California 94063
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 995-8200

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On April 17, 2017, OncoMed Pharmaceuticals, Inc. (the "Company") announced its cash and short-term investment balance for the quarter ended March 31, 2017. The full text of the press release issued in connection with the announcement (the "Press Release") is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is located on the Company's website at www.oncomed.com under "Investors – Press Releases."

The information in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 8.01. Other Events.

On April 17, 2017, in the Press Release, the Company also announced top-line results from the Company's randomized 145-patient Phase 2 PINNACLE clinical trial of tarextumab (anti-Notch2/3, OMP-59R5) in combination with etoposide plus either cisplatin or carboplatin chemotherapy in previously untreated patients with extensive-stage small cell lung cancer, as well as a conference call/webcast to review these results. The Company further reported in the Press Release that it will discontinue enrollment in the Phase 1b clinical trial of brontictuzumab (anti-Notch1, OMP-52M51) in combination with trifluridine/tipiracil (Lonsurf ®) in third-line colorectal cancer patients. The first, third, and fifth paragraphs of the Press Release are incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits .

Exhibit No.	Description
99.1	Press release dated April 17, 2017 entitled "OncoMed's Phase 2 Trial of Tarextumab in Small Cell Lung Cancer Does Not Meet Endpoints"

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 17, 2017

ONCOMED PHARMACEUTICALS, INC.

By: /s/ Alicia J. Hager
Alicia J. Hager, J.D., Ph.D.
Senior Vice President and General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated April 17, 2017 entitled "OncoMed's Phase 2 Trial of Tarextumab in Small Cell Lung Cancer Does Not Meet Endpoints"

Exhibit 99.1

FOR IMMEDIATE RELEASE

OncoMed's Phase 2 Trial of Tarextumab in Small Cell Lung Cancer Does Not Meet Endpoints

Company also Announces Discontinuation of Brontictuzumab Phase 1b Study

OncoMed Management to Host Conference Call/Webcast at 8:30 a.m. ET/5:30 a.m. PT to Review Top-line Results

REDWOOD CITY, Calif., April 17, 2017 – OncoMed Pharmaceuticals, Inc. (Nasdaq: OMED), a clinical-stage biopharmaceutical company focused on discovering and developing novel anti-cancer stem cell and immuno-oncology therapeutics, today reported top-line results from the company's randomized 145-patient Phase 2 PINNACLE clinical trial of tarextumab (anti-Notch2/3, OMP-59R5) in combination with etoposide plus either cisplatin or carboplatin chemotherapy ("chemotherapy") in previously untreated patients with extensive-stage small cell lung cancer. Results for the combination of tarextumab plus chemotherapy were undifferentiated from those of chemotherapy plus placebo, and therefore the trial did not meet its primary endpoint of progression-free survival or secondary endpoints of overall survival and biomarkers reflective of Notch pathway gene activation .

"Small cell lung cancer is a very difficult-to-treat disease and unfortunately, tarextumab did not show benefit over placebo in this Phase 2 trial," said Paul J. Hastings, OncoMed's Chairman and CEO. "We deeply appreciate the participation by the investigators and staff, patients and caregivers who all contributed to the conduct and completion of this Phase 2 clinical trial."

OncoMed also announced today that it will discontinue enrollment in the Phase 1b clinical trial of brontictuzumab (anti-Notch1, OMP-52M51) in combination with trifluridine/tipiracil (Lonsurf ®) in third-line colorectal cancer patients. The combination of brontictuzumab plus chemotherapy was not tolerable in this patient population.

"Based on the events of today and last week, we will be undertaking a comprehensive portfolio prioritization review immediately," continued Mr. Hastings. "The immediate task ahead is to thoroughly examine the available data, our resources and the opportunities to re-focus our efforts. We ended the first quarter of 2017 with $156.9 million in cash and short-term investments."

The median progression-free survival (mPFS) for tarextumab plus chemotherapy was 5.6 months versus 5.5 months for chemotherapy plus placebo (HR=0.969). T he median overall survival (mOS) analysis did not show a benefit for tarextumab in combination with chemotherapy (mOS=9.3 months) compared to the chemotherapy plus placebo arm (10.3 months; HR=1.01). Five individual Notch biomarkers (Hes1, Hes6, Hey1, Hey2 and Notch3) failed to identify a definitive subset of patients with a treatment effect on either mPFS or mOS. Overall response rates were 68.5% and 70.8% in the tarextumab and placebo arms respectively. The combination of tarextumab plus chemotherapy was well tolerated. The safety profile appeared to be similar between the two groups except for diarrhea and thrombocytopenia, which were more prevalent in the tarextumab treatment arm, and constipation, which was more prevalent in the placebo arm.

OncoMed management will host a conference call today at 8:30 a.m. ET/5:30 a.m. PT to discuss the PINNACLE clinical trial data. OncoMed plans to present full study findings, including results from the biomarker analyses, at a future scientific conference.

About the Phase 2 PINNACLE Trial

Patients enrolled in the randomized, double-blinded, multi-center PINNACLE clinical trial were randomized into two study arms and received either 15mg/kg of tarextumab every three weeks in combination with six cycles of etoposide and either cisplatin or carboplatin chemotherapy followed by tarextumab maintenance to progression or six cycl es of chemotherapy and a placebo. The primary endpoint of the trial was progression-free survival. Secondary endpoints included overall survival and overall response rate, pharmacokinetics, safety and biomarker analyses. Overall survival, progression-fr ee survival and overall response rates are also being assessed against elevated tumor expression of the Notch pathway genes Hes1, Hes6, Hey1, Hey2 and Notch3 as a secondary endpoint. The PINNACLE trial was conducted at 36 sites in the United States.

Conference Call Today
OncoMed management will host a conference call today beginning at 8:30 a.m. ET/5:30 a.m. PT to review top-line results from the Phase 2 PINNACLE clinical trial.

Analysts and investors can participate in the conference call by dialing 1-855-420-0692 (domestic) and 1-484-756-4194 (international) using the conference ID# 9336875. A webcast of the conference call will be accessible through a link in the Investor Relations section of the OncoMed website: http://www.oncomed.com . An audio replay of the conference call can be accessed by dialing 1-855-859-2056 (domestic) or 1-404-537-3406 utilizing the conference ID number listed above. The web broadcast of the conference call will be available for replay through 90 days via the OncoMed website.

About Tarextumab (anti-Notch2/3, OMP-59R5)
Tarextumab (anti-Notch2/3, OMP-59R5) is a fully human monoclonal antibody that targets the Notch2 and Notch3 receptors. Preclinical studies suggested that tarextumab exhibits two mechanisms of action: (1) by downregulating Notch pathway signaling, tarextumab appears to have anti-cancer stem cell effects, and (2) tarextumab affects pericytes, impacting stromal and tumor microenvironment. Tarextumab is part of OncoMed's collaboration with GlaxoSmithKline (GSK).

About Small Cell Lung Cancer
According to the American Cancer Society, lung cancer (both small cell and non-small cell) is the second most common cancer in men and women and is by far the leading cause of cancer death. Small cell lung cancer is expected to make up about 10%-15% of the 224,390 newly diagnosed lung cancer cases and the 158,080 deaths estimated to occur in the U.S. in 2016. Small cell lung cancer tends to grow and spread quickly, and is typically not discovered until it has metastasized to other parts of the body (extensive stage). The current standard of care in treating small cell lung cancer is the chemotherapeutic etoposide in combination with either cisplatin or carboplatin. In spite of a high sensitivity to chemotherapy and remission rates of up to 80% following initial treatment, the median overall survival is less than one year for patients with extensive stage disease [1] .

About OncoMed Pharmaceuticals
OncoMed Pharmaceuticals is a clinical-stage biopharmaceutical company focused on discovering and developing novel anti-cancer stem cell and immuno-oncology therapeutics. OncoMed has internally discovered a deep pipeline of investigational drugs intended to address the fundamental biology driving cancer's growth, resistance, recurrence and metastasis. As part of a broad strategic alliance with Celgene Corporation, the company is developing demcizumab (anti-DLL4, OMP-21M18), navicixizumab (anti-DLL4/VEGF bispecific, OMP-305B83), rosmantuzumab (anti-RSPO3, OMP-131R10) and anti-TIGIT (OMP-313M32). OncoMed is independently developing several other therapeutic candidates while pursuing drug discovery research. For further information about OncoMed Pharmaceuticals, please see www.oncomed.com .

1 Jänne PA, Freidlin B, Saxman S, et al. Cancer 2002; 95:1528-38.

Forward-Looking Statements
To the extent that statements contained in this press release are not descriptions of historical facts regarding OncoMed Pharmaceuticals, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, without limitation, OncoMed's intentions and expectations regarding its portfolio prioritization review; OncoMed's examination of data, resources and the opportunities to re-focus its efforts; discontinuation of enrollment in the brontictuzumab trial; and OncoMed's future

presentation of full study findings. Such forward-looking statements involve substantial risks and uncertainties that could cause OncoMed's clinic al development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the preclinica l and clinical development process; OncoMed's dependence on its collaboration partners for the funding of its partnered programs; OncoMed's ability to raise additional capital to support the development of its unpartnered programs; OncoMed's reliance on th ird parties to conduct all of its clinical trials; OncoMed's reliance on single source third-party contract manufacturing organizations to manufacture and supply its product candidates; and OncoMed's dependence on its key executives. OncoMed undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to OncoMed 's business in general, see OncoMed's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 9, 2017 and OncoMed's other current and periodic reports filed with the SEC.

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